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| EXAMINER | |
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| ROYDS, LESLIE A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/700,784 | DULIN, JACQUES M. | |
| | Examiner | Art Unit | |
| | Leslie A. Royds | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5 and 16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *27 March 2006* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

**Claims 1-20 are presented for examination.**

**Applicant's petition to make the instant application special under 37 C.F.R. 1.102(c)(1) has previously been acknowledged by the Examiner at page 2 of the previous Office Action dated November 16, 2005.**

Applicant's Amendment filed June 5, 2006 and the updated declaration filed February 14, 2006 have each been received and entered into the application. Accordingly, the specification at page 1 has been amended and claims 1, 3, 6-7, 10, 12, 14, 16 and 19-20 have also been amended.

In view of the amendments, particularly the amendment changing the transitional claim language from "comprising" to "consisting essentially of", and the remarks made herein, the objections to the oath/declaration and the specification; the rejection of claims 7, 9 and 14 under 35 U.S.C. 112, second paragraph; the rejection of claims 1-4 and 7 under 35 U.S.C. 102(b); and the rejection of claims 1-4 and 6-15 under 35 U.S.C. 103(a), as set forth at pages 4-15 of the previous Office Action dated November 16, 2005, have each been hereby **withdrawn**.

***Proper Form and Conduct for the Submission of Amendments to the Record***

Applicant is reminded of 37 C.F.R. 1.3, which expressly states:

"*§1.3 Business to be conducted with decorum and courtesy.* Applicants and their attorneys or agents are required to conduct their business with the United States Patent and Trademark Office *with decorum and courtesy. Papers presented in violation of this requirement will be submitted to the Director and will not be entered.* A notice of the non-entry of the paper will be provided. Complaints against examiners and other employees must be made in

correspondence separate from other papers. [Amended, 61 FR 56439, Nov. 1, 1996, effective Dec. 2, 1996; revised, 68 FR 14332, Mar. 25, 2003, effective May 1, 2003; revised, 68 FR 38611, June 30, 2003, effective July 30, 2003]." (emphasis added)

***Requirement for Restriction/Election***

Restriction of the present claims was required under 35 U.S.C. 121 into two groups:

I. Claims 1-15, drawn to a medication delivery system for oral hygiene and a portable consumer package containing such a delivery system, classified in class 514, subclass 568, for example.

II. Claims 16-20, drawn to a method for oral hygiene care, classified in class 514, subclass 568, for example.

During a telephone conversation with Jacques Dulin on Wednesday, November 9, 2005, a provisional election was understood to be made **without traverse** to prosecute the invention of Group I claims 1-15, drawn to a medication delivery system for oral hygiene and a portable consumer package containing such a delivery system, and the species of benzoic acid as the active ingredient contained within the treatment composition.

Applicant now alleges that the election of the invention of Group I was made **with traverse** and states that the traversal is on the grounds that the inventions of Groups I and II are a single invention and that the Examiner has not shown that the claims to the product and its methods of use are patentably distinct inventions. Applicant also traverses based upon the fact that the inventions of Groups I and II share a common classification.

Applicant's traverse has been carefully considered in its entirety, but is not found persuasive. The medication delivery system of Group I (claims 1-15) is a patentably distinct invention from the method of Group II (claims 16-20). The invention of Group I is related to the invention of Group II as a product and a process of use. The MPEP states, "a product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using the product as claimed can be practiced with another materially different product; **or** (B) the product as claimed can be used in a materially different process" (MPEP §806.02(h)). The claimed product can be employed in a materially different process, such as insertion of the cotton roll impregnated with the antimicrobial agent, benzoic acid, directly into a wound as a plug to promote antimicrobial action and healing. It is again stated on the record that intended uses or intended functions of a composition do not impart patentable distinction unless they structurally or materially alter the physical nature of the composition. Thus, the fact that Applicant intends to the use the claimed cotton roll for oral hygiene does not structurally or materially alter the physical nature of the composition. Because the composition as claimed can be used to practice another materially different process, the inventions of Groups I and II are held to be patentably distinct in accordance with the MPEP at §806.02(h).

Applicant is reminded that the restriction of the present claims does not rest on the separate classification of the invention of Group I and the invention of Group II. The Examiner has not relied upon the classification of the subject matter in order to demonstrate patentable distinction between the inventions. The very fact that the inventions of Groups I and II are drawn to divergent subject matter such that each is differently searched and would not

necessarily result in a comprehensive search of the other invention is sufficient to establish patentable distinction between the groups. Thus, Applicant's traversal on the grounds that the inventions of Groups I and II share a common classification and, therefore, should be examined together is not found persuasive since the inventions have been held to be patentably distinct for the reasons already made of record (please see the preceding paragraphs and the previous Office Action dated November 16, 2005 at pages 2-4).

Applicant also now alleges that the election of species was made **with traverse** and traverses the species election by alleging the provisional election of "antimicrobial compound or compositions" as stated in line 2 of present claim 3, not the election of the species of "benzoic acid". However, Applicant expressly stated the election of "the antimicrobial agent benzoic acid" as the single disclosed species of active ingredient contained within the treatment composition during the telephone conversation on Wednesday, November 9, 2005. Examination of the present claims was performed herein to the extent that it read upon the use of benzoic acid *per se* as the active agent of the treatment composition.

Applicant is reminded that the compound benzoic acid is, itself, an antimicrobial compound, whose antimicrobial effects were well recognized in the art well before the present invention (please reference Vermeer, U.S. Patent No. 5,624,906, 1997 at col.35, line 66-col.36, line 30, in particular, col.36, line 20; previously cited by the Examiner). Thus, the genus of "antimicrobial compound or compositions" has been examined insofar as it reads upon the elected species of benzoic acid *per se*.

Applicant asserts that present claim 5 should not be withdrawn because both compositions of claim 5 are antimicrobial agents. Applicant was given the choice to elect a

single disclosed species from the generic claims 3, 5-6 and 18-19, which clearly provided Applicant with the choice of electing the specific species of "benzoic acid-type mouthwash" as recited in present claim 5 or the specific species of "benzoic acid" as recited in present claim 6. Consistent with the provisional election that Applicant stated during the telephone conversation Wednesday, November 9, 2005, examination of the present claims was performed to the extent that the present claims read upon the use of benzoic acid *per se*. Present claim 5 is drawn to the use of a "at least one of a boric acid-type mouthwash and a benzoic acid-type mouthwash", which does not read upon the elected species. In particular, it is noted that the limitation "benzoic acid-type" of the phrase "benzoic acid-type mouthwash" reads upon any mouthwash with any degree of similarity to benzoic acid, but is not necessarily benzoic acid *per se*. Moreover, it is further limited by the fact that is in a mouthwash formulation, which was not expressly stated as the provisionally elected species. In other words, present claim 5 does not read upon the elected subject matter and remains properly withdrawn from consideration.

Applicant's statement that, "Upon allowance of the 'anti-microbial' species, per the MPEP, up to 5 additional species must be examined, and that covers all the 'species' of claim 3" at page 3 of the remarks has been considered, but fails to find support in the guidance or the teachings of the MPEP. Applicant alleges that this assertion that "5 additional species must be examined" is in accordance with the MPEP, but does not provide a citation to the section in which it can be found. In light of such, traversal upon these grounds will not be further considered.

Applicant is also reminded of MPEP §819, which states, "The general policy of the Office is not to permit the applicant to shift to claiming another invention after an election is

once made and action given on the elected subject matter." In accordance with the guidance of the MPEP at §819, election of "benzoic acid" has been noted as the single disclosed elected species and action has been given on this elected subject matter. Thus, Applicant is not permitted to now elect the genus of "antimicrobial compound or compositions", since that was not the species originally elected.

Therefore, for the reasons above and those of record, the restriction requirement is proper and is, therefore, made **FINAL**.

Claims 5 and 16-20 are **withdrawn** from further consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to a non-elected invention.

The claims that are drawn to the elected invention and elected species of active ingredient are 1-4 and 6-15 and prosecution of those claims follows herein.

***Claim Rejections - 35 USC § 103 (New Ground of Rejection)***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masci et al. (U.S. Patent No. 3,147,182; 1964) in view of Wiesel (U.S. Patent No. 6,287,120, 2001; previously cited), Vermeer (U.S. Patent No. 5,624,906, 1997; previously cited), Julius (U.S. Patent No. 4,071,955, 1978; previously cited), Speaker et al. (U.S. Patent No. 4,917,892, 1990; previously cited) and Copelan et al. (U.S Patent No. 5,133,971, 1992; previously cited).

Masci et al. teaches improved antimicrobial compositions for controlling bacteria and other microorganisms, wherein the composition contains a decamethylene 1,10-bis-4-aminoquinaldinium salt (col.1, lines 11-15) and a cetyl pyridinium salt (col.2, lines 55-57), and further wherein the composition may be dry, as in the case of an antiseptic dusting powder (col.8, lines 6-12), or aqueous, as in the case of a solution (col.8, lines 20-22), and, additionally, wherein the active composition is incorporated into or applied to dental articles, such as cotton rolls (col.8, lines 12-16).

The differences between the Masci et al. reference and the presently claimed subject matter lie in that the reference fails to teach the active composition in a gel state (see present claim 2); the use of benzoic acid as the active antimicrobial ingredient (see present claim 6); the use of a cotton roll including a core of absorbent cotton fibers and a sheath selected from a mesh braiding and a highly permeable woven or non-woven sheet material (see present claim 8); or a portable consumer package of the type presently claimed (see present claims 10-15).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains for the following reasons:

The use of a gel formulation of the active composition to be applied directly to the teeth or inserted into the oral cavity would have been *prima facie* obvious to one of ordinary skill in the art because the skilled artisan would have been motivated to increase the therapeutic benefit of the composition by increasing the viscosity of the composition into a gel state to increase the resident time of the active composition in contact with the teeth, which, in turn, would enhance

efficacy. This is supported by the teachings of Wiesel (U.S. Patent No. 6,287,120; 2001), who discloses a delivery system of a non-woven, porous material impregnated or coated with an agent in the form of a gel to be applied to the teeth as a novel solution to the loss of efficacy seen when topical solutions are applied to the teeth or oral cavity (col.3, lines 66-67 and col.4, lines 5-17). In particular, Wiesel states, "Topically applied antiseptics, such as mouthwashes, are easily washed from the site of infection by salivation and routine mastication. Thus, a need exists for an oral composition which is effective in combating growth of infection causing bacteria which is capable of adhering to the site of the infection and being retained in the oral cavity." (col.2, line 64-col.3, line 7). In light of such a teaching, the use of a gel formulation of the active composition would have naturally commended itself to one of ordinary skill in the art motivated to enhance the therapeutic efficacy of the composition with a reasonable expectation that a greater therapeutic benefit could be achieved using a gel formulation rather than an aqueous formulation of the active composition, since aqueous solutions are easily washed away from the site to be treated.

Regarding the use of benzoic acid as the antimicrobial agent applied to or incorporated into the dental cotton roll, the use of such an agent as the antiseptic component of the active cotton roll composition of Masci et al. would have been *prima facie* obvious to one of ordinary skill in the art because Vermeer (U.S. Patent No. 5,624,906; 1997) teaches benzoic acid as an antibacterial agent commonly used in oral hygiene compositions, which was known to have activity against a wide variety of microorganisms at levels below those known to be harmful (col.35, line 66-col.36, line 30; see, in particular, col.36, line 20). In light of such a teaching, the skilled artisan would have been motivated to employ benzoic acid as the antiseptic component of

the impregnated cotton roll composition of Masci et al. because there would have been a reasonable expectation of success that benzoic acid would have provided broad-spectrum antibacterial activity against a variety of different microorganisms, in addition to the fact that such a compound could be employed at concentrations lower than those that cause harmful or toxic effects while still preserving its antibacterial effect.

Respecting the use of a cotton roll with a core of absorbent cotton fibers and a sheath selected from a mesh braiding and a highly permeable woven or non-woven sheet material, the use of such a cotton roll/sheath combination would have been *prima facie* obvious to one of ordinary skill in the art because Julius (U.S. Patent No. 4,071,955; 1978) teaches that absorbent sponge-like material laminated with at least one layer of woven or non-woven fabric-like material, such as cotton gauze or cotton batting, has the advantage of absorbing more than a conventional sponge composition and does not leave lint behind in the oral cavity (see abstract; col.2, lines 7-10 and 32-34). In addition, Speaker et al. (U.S. Patent No. 4,917,892; 1990) provides teachings that braided cord was commonly used in dental applications to provide highly sustained localized topical drug delivery and to serve as a drug reservoir (col.1, lines 55-61). In light of such teachings, the skilled artisan would have been motivated to employ the cotton roll of Masci et al. with an outer covering of either a woven or non-woven fabric material, such as cotton gauze or batting, to enhance the absorbency of the cotton roll in retaining the active antiseptic composition, or a braided cord, to enhance the amount of active antiseptic composition retained in the cotton roll and to sustain localized topical delivery of the composition over a longer period of time, as well as to eliminate any lint left behind in the oral cavity from the absorbent cotton roll.

The present claims are drawn also to a portable consumer package comprising a sealed, water-impervious pouch containing a plurality of single use cotton rolls impregnated with benzoic acid, wherein the pouch is pocket-sized and contains a tear-off strip and a zip closure for resealing the pouch, and further wherein a plurality of said pouches are packaged in a box. Applicant is reminded that the type of packaging in which the composition is retained fails to impart any physical, material or structural properties to the composition that are not found in the prior art of Masci et al. and, therefore, do not constitute a patentable distinction over the art.

However, regarding such limitations, Copelan et al. (U.S Patent No. 5,133,971; 1992) provides teachings of a simple, edge sealed packet of protective material, such as coated or uncoated paper that is adhesively or mechanically bonded at its edges to form a rectangular pouch, wherein the packet may be made of foil or moisture impervious sheet plastic material (col.4, lines 28-37), used to carry cotton fiber mats impregnated with cleansing agents (col.4, lines 63-66).

In light of this teaching, the use of such a packaging form to carry the cotton rolls of Masci et al. impregnated with the active antiseptic composition would have been *prima facie* obvious to one of ordinary skill in the art because the skilled artisan would have been motivated to elect such a package in order to facilitate distribution of the impregnated cotton rolls while preserving the sterility of the rolls prior to insertion into the mouth, as well as to retain the efficacy of the impregnated cotton roll by protecting them from contacting water, which would activate the impregnated antiseptic agent prior to actual use. Furthermore, one of ordinary skill in the art would have also been motivated to modify such a package to make it resealable in order to preserve sterility of a plurality of cotton rolls contained within such a package for use at

a later time, as well as pocket-sized, such that the rolls could be easily and discretely transported on one's person. In addition, the overall packaging of such pouches into a box would have been *prima facie* obvious to the skilled artisan motivated by a need to ship, transport or move a volume of cotton rolls in order to facilitate distribution.

Lastly, the determination of the optimum diameter or length of the cotton roll to be employed in the disclosed composition would have been a matter well within the purview of the skilled artisan. Such a determination would have been made in accordance with a variety of factors, including, but not limited to, the size of the subject's mouth, the medicament impregnated into the cotton roll and the dose of the medicament to be administered. Moreover, Applicant is reminded that where the only difference between the prior art and the claims is a recitation of the relative dimensions of the claimed composition, and wherein such a difference in the dimensions does not result in an appreciable difference in function of the composition, then the presently claimed dimensions do not patentably distinguish the presently claimed composition from that of the cited prior art.

Applicant has amended present claims 1 and 10 to now recite "upon insertion in a buccal vestibule for an extended period of time and action by a buccinator muscle, said treatment composition is expressed and leaches from said roll to bathe oral tissues, teeth surfaces and gingival sulcus, and stimulates saliva production, thereby effecting treatment of said periodontal condition". This is a statement of the intended use of the composition. The intended use of a composition must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the present case,

Applicant's intent to insert the composition of a cotton roll impregnated with benzoic acid into the buccal vestibules of the mouth does not physically or materially alter the structure of the presently claimed composition. If anything, the only structural requirement is that the composition must be amenable to use in the oral cavity. This limitation is met by the cited art. Applicant is reminded that present claims are drawn to a composition of matter comprising, in its broadest embodiment, a cotton roll impregnated with benzoic acid in an effective amount.

As taught by the MPEP at §2111.02[R-2]:

"*If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction*...During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art...If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim." (emphasis added)

It is clear from the present case that the cited references do fully, unequivocally and intrinsically set forth, or render obvious, each and every physical and structural limitation of the presently claimed composition. Thus, following the direction of the MPEP at §2111.02[R-2], the intended use of the composition is not considered a material or structural limitation of the

presently claimed composition. Absent factual evidence to the contrary, the prior art structure is capable of performing the intended use and, thus, meets the claims.

***Conclusion***

The prior art made of record but not relied upon is considered pertinent to Applicant's disclosure. Please reference U.S. Patent No. 4,175,326 (1979) to Goodson, entitled "Hollow-Fiber Devices For and a Method of the Treatment and Diagnosis of Oral Diseases".

Rejection of claims 1-4 and 6-15 is proper and is **maintained**.

This application contains claims 5 and 16-20 drawn to an invention non-elected with traverse as stated in the response filed June 5, 2006. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action pursuant to 37 C.F.R. 1.144. Please reference MPEP §821.01.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

June 8, 2006

Ardin H. Marschel 6/11/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER